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| EXAMINER | |
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| BUSS, BENJAMIN J | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/681,585 | GOGOLAK, VICTOR | |
| | Examiner | Art Unit | |
| | BENJAMIN BUSS | 2129 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *3/11/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5,7-12,14-26 and 28-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-12,14-26 and 28-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

This Office Action is in response to an AMENDMENT filed 3/11/2008 for the patent application 09/681,585 filed on **5/2/2001**. The Office Action of 7/13/2007 is fully incorporated into this Office Action by reference. Claims 1-5, 7-12, 14-16, and 28-41 are pending.

### ***Claim Objections***

Claims 33-36 and 40 are objected to because of the following informalities:

- Claim 33 line 10: Change "supplements and" to – supplements, and --.
- Claim 34 line 3: Change "the drug of interest" to – the substance of interest --.
- Claim 34 line 5: Change "identifies a one" to – identifies one --.
- Claim 35 line 3: Change "to label the one or more drugs are labeled as" to – to label each of the one or more drugs as --.
- Claim 36 line 3: Change "or more drugs are labeled" to – or more drugs labeled --.
- Claim 40 line 6: Change "terms; and" to – terms; --.
- Claim 40 line 8: Change "drug effect." to – drug effect; and --.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

#### ***Response to Arguments***

Applicant's arguments, see page 14, filed 7/13/2006, with respect to the rejections under 35 U.S.C. §112, second paragraph, have been fully considered and are persuasive. The rejection of claims 4, 11, 18, 20-21, and 25 under 35 U.S.C., second paragraph, has been withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by **Szarfman** ("New Methods for Signal Detection").

**Claim 15:**

**Szarfman** anticipates:

- a selector for identifying a least one drug of interest (p1-56 especially "Detection of 'higher than expected' signal scores" p23 or "data extraction" p32 or "scores … associated with a specific drug" p48);
- a profiler for selecting from multiple profiles related to safety of the at least one drug of interest, using at least one filter to determine at lest one set of cases (p1-56 especially "Drug-event combinations by drug, drug class, event, event group, and time interval" p23 or "stratification" p28 or "age specific exposure" p30 or "derived from application of a statistical model to identify the ones observed at higher than expected frequencies" p32);
- at least one data mining engine for processing the at least one set of cases determined and submitted by the at least one filter (p1-56 especially "Data Mining" p23 or "identifying and documenting many serious rare adverse drug reactions" p26 or "gender-based patterns" p29 or "estimate SS" p32 or "model ***DERIVED*** from the data" p42); and
- an output device for displaying analytic results from the data mining engine (p1-56 especially "each distinct combination of any drug, event, sex, time, and age group" p35 or "predict patients at risk" p56).

**Claim 16:**

**Szarfman** anticipates:

- wherein the at least one data mining engine is a proportional analysis engine to assess deviations in a set of the reactions to the drug of interest (p1-56 especially p43 or p48).

**Claim 17:**

**Szarfman** anticipates:

- wherein the data mining engine is a comparator to measure reactions to the drug of interest against a user-defined backdrop (p1-56 especially p51 or p53).

**Claim 18:**

**Szarfman** anticipates:

- wherein the data mining engine is a correlator to look for correlated signal characteristics in at least one of drug information, reaction information, and demographic information (p1-56 especially p23 or p32 or p35 or p42 or p49).

**Claim 19:**

**Szarfman** anticipates:

- wherein the data mining engine is at least two members of the group consisting of: a proportional analysis engine (p1-56 especially p43 or p48), a comparator (p1-56 especially p51 or p53), and a correlator (p1-56 especially p23 or p32 or p35 or p42 or p49).

**Claim 21:**

**Szarfman** anticipates:

- wherein the system permits assessment and analysis of risks of adverse effects resulting from use of at least one drug of interest in any of multiple dimensions of risk assessment and analysis (p1-56 especially p32 or p42 or p49).

## ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-12, 14, 20, 22-26, 28-30, 32-35, and 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Szarfman** ("New Methods for Signal Detection") and **Classen** (USPN 6,219,674).

**Claims 1, 8, and 22:**

**Szarfman** teaches:

- a selector for identifying a least one drug of interest (p1-56 especially "Detection of 'higher than expected' signal scores" p23 or "data extraction" p32 or "scores … associated with a specific drug" p48);
- a profiler for selecting from multiple profiles related to safety of the at least one drug of interest, using at least one filter to determine at lest one set of cases (p1-56 especially "Drug-event combinations by drug, drug class, event, event group, and time interval" p23 or "stratification" p28 or "age specific exposure" p30 or "derived from application of a statistical model to identify the ones observed at higher than expected frequencies" p32);
- at least one data mining engine for processing the at least one set of cases determined and submitted by the at least one filter (p1-56 especially "Data Mining" p23 or "identifying and documenting many serious rare adverse drug reactions" p26 or "gender-based patterns" p29 or "estimate SS" p32 or "model ***DERIVED*** from the data" p42);
- an output device for displaying analytic results from the data mining engine (p1-56 especially "each distinct combination of any drug, event, sex, time, and age group" p35 or "predict patients at risk" p56); and
- wherein the substance of interest is assessed in combination with other drugs, chemicals, and hormones (p1-56 especially i.e. pages 23, 32, 35, 38, 42, or 50).

**Szarfman** fails to teach:

- wherein the substance of interest is assessed in combination with foodstuffs, beverages, nutrients, vitamins, toxins, and supplements.

**Classen** teaches:

- wherein the substance of interest is assessed in combination with other drugs, foodstuffs, beverages, nutrients, vitamins, toxins, chemicals, hormones, and supplements (C1-12 especially i.e. C5L10-18 or C6L9-30 or C6L55-C7L25).

Rationale:

**Szarfman** and **Classen** are from the same field of endeavor, detecting adverse effects of drugs. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of **Szarfman** by assessing the substance of interest in combination with other drugs, foodstuffs, beverages, nutrients, vitamins,

toxins, chemicals, hormones, and supplements as taught by **Classen** for the benefit of identifying new uses or restrictions for medical products (**Classen** C3L13-21).

**Claims 2, 9, and 23:**

**Szarfman** teaches:

- wherein the at least one data mining engine is a proportional analysis engine to assess deviations in a set of the reactions to the drug of interest (p1-56 especially p43 or p48).

**Claims 3, 10, and 24:**

**Szarfman** teaches:

- wherein the data mining engine is a comparator to measure reactions to the drug of interest against a user-defined backdrop (p1-56 especially p51 or p53).

**Claims 4, 11, and 25:**

**Szarfman** teaches:

- wherein the data mining engine is a correlator to look for correlated signal characteristics in at least one of drug information, reaction information, and demographic information (p1-56 especially p23 or p32 or p35 or p42 or p49).

**Claims 5, 12, and 26:**

**Szarfman** teaches:

- wherein the data mining engine is at least two members of the group consisting of: a proportional analysis engine (p1-56 especially p43 or p48), a comparator (p1-56 especially p51 or p53), and a correlator (p1-56 especially p23 or p32 or p35 or p42 or p49).

**Claims 7, 14, and 28:**

**Szarfman** teaches:

- wherein the system permits assessment and analysis of risks of adverse effects resulting from use of at least one drug of interest in any of multiple dimensions of risk assessment and analysis (p1-56 especially p32 or p42 or p49).

**Claim 20:**

**Szarfman** teaches:

- wherein the substance of interest is assessed in combination with other drugs, chemicals, and hormones (p1-56 especially i.e. pages 23, 32, 35, 38, 42, or 50).

**Szarfman** fails to teach:

- wherein the substance of interest is assessed in combination with foodstuffs, beverages, nutrients, vitamins, toxins, and supplements.

**Classen** teaches:

- wherein the substance of interest is assessed in combination with other drugs, foodstuffs, beverages, nutrients, vitamins, toxins, chemicals, hormones, and supplements (C1-12 especially i.e. C5L10-18 or C6L9-30 or C6L55-C7L25).

Rationale:

**Szarfman** and **Classen** are from the same field of endeavor, detecting adverse effects of drugs. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of **Szarfman** by assessing the substance of interest in combination with other drugs, foodstuffs, beverages, nutrients, vitamins, toxins, chemicals, hormones, and supplements as taught by **Classen** for the benefit of identifying new uses or restrictions for medical products (**Classen** C3L13-21).

**Claim 29:**

**Szarfman** teaches:

- wherein the proportional analysis further comprises comparing the drug of interest to a second drug of interest in the same therapeutic category for the drug of interest selected (p1-56 especially i.e. pages 23, 52, or 53).

**Classen** teaches:

- wherein the proportional analysis further comprises comparing the drug of interest to a second drug of interest in the same therapeutic category for the drug of interest selected (C1-12 especially i.e. C3L24-C4L14 or C6L55-67 or C12L45-55).

**Claim 30:**

**Szarfman** teaches:

- wherein the proportional analysis further comprises comparing the drug of interest to a second drug of interest in a second therapeutic category (p1-56 especially i.e. pages 51, 52, or 53).

**Classen** teaches:

- wherein the proportional analysis further comprises comparing the drug of interest to a second drug of interest in a second therapeutic category (C1-12 especially i.e. C3L24-C4L14 or C4L60-65 or C5L10-18 or C6L9-30 or C6L55-C7L25 or C12L45-55).

**Claim 30:**

**Szarfman** teaches:

- wherein the proportional analysis further comprises comparing the drug of interest to a second drug of interest in a second therapeutic category (p1-56 especially i.e. pages 51, 52, or 53).

**Classen** teaches:

- wherein the proportional analysis further comprises comparing the drug of interest to a second drug of interest in a second therapeutic category (C1-12 especially i.e. C3L24-C4L14 or C4L60-65 or C5L10-18 or C6L9-30 or C6L55-C7L25 or C12L45-55).

**Claims 32 and 33:**

**Szarfman** teaches:

- a selector for identifying a least one drug of interest (p1-56 especially “Detection of ‘higher than expected’ signal scores” p23 or “data extraction” p32 or “scores … associated with a specific drug” p48);

- a profiler for selecting from multiple profiles related to safety of the at least one drug of interest, using at least one filter to determine at lest one set of cases (p1-56 especially “Drug-event combinations by drug, drug class, event, event group, and time interval” p23 or “stratification” p28 or “age specific exposure” p30 or “derived from application of a statistical model to identify the ones observed at higher than expected frequencies” p32);
- at least one data mining engine for processing the at least one set of cases determined and submitted by the at least one filter (p1-56 especially “Data Mining” p23 or “identifying and documenting many serious rare adverse drug reactions” p26 or “gender-based patterns” p29 or “estimate SS” p32 or “model ***DERIVED*** from the data” p42); and
- an output device for displaying analytic results from the data mining engine (p1-56 especially “each distinct combination of any drug, event, sex, time, and age group” p35 or “predict patients at risk” p56);
- wherein the substance of interest is assessed in combination with other drugs, chemicals, and hormones (p1-56 especially i.e. pages 23, 32, 35, 38, 42, or 50); and
- wherein the assessment of the substance of interest includes comparing the potential and actual adverse effects of a substance of interest in a pre-market environment to that of the potential and actual adverse effects of a substance of interest in a post-market environment (p1-56 especially i.e. pages 11, 13, 19, 23-24, 26, or 53).

**Szarfman** fails to teach:

- wherein the substance of interest is assessed in combination with foodstuffs, beverages, nutrients, vitamins, toxins, and supplements.

**Classen** teaches:

- wherein the substance of interest is assessed in combination with other drugs, foodstuffs, beverages, nutrients, vitamins, toxins, chemicals, hormones, and supplements (C1-12 especially i.e. C5L10-18 or C6L9-30 or C6L55-C7L25).
- wherein the assessment of the substance of interest includes comparing the potential and actual adverse effects of a substance of interest in a pre-market environment to that of the potential and actual adverse effects of a substance of interest in a post-market environment (C1-12 especially i.e. C5L60-C6L10 or C6L55-C7L25 or C9L35-62 or claim 47)

Rationale:

**Szarfman** and **Classen** are from the same field of endeavor, detecting adverse effects of drugs. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of **Szarfman** by assessing the substance of interest in combination with other drugs, foodstuffs, beverages, nutrients, vitamins, toxins, chemicals, hormones, and supplements as taught by **Classen** for the benefit of identifying new uses or restrictions for medical products (**Classen** C3L13-21).

**Claim 34:**

**Szarfman** teaches:

- wherein the substance of interest identified by the selector is a target drug (p1-56 especially i.e. "scores … associated with a specific drug" p4 or p23 or "data extraction" p32);
- wherein the profiler identifies one or more drug dimensions (p1-56 especially p32 or 42 or pp46-49 or p52);
- wherein the one or more prescriptions are configured to result in an adverse drug reaction report (p1-56 especially i.e. p29 or pp46-48); and
- wherein the adverse drug reaction is configured so as to be reported in an adverse effects reporting database (p1-56 especially i.e. p11).

**Szarfman** fails to teach:

- wherein the target drug is profiled in relation to one or more concomitant drugs;
- wherein the one or more concomitant drugs were prescribed in one or more cases where the target drug was also prescribed.

**Classen** teaches:

- wherein the substance of interest identified by the selector is a target drug (C1-12 especially i.e. C7L1-30);
- wherein the target drug is profiled in relation to one or more concomitant drugs (C1-12 especially i.e. C6L30-40 or C6L55-67 or "patients taking the drug along with one or more additional drugs" C7L1-30);
- wherein the one or more concomitant drugs were prescribed in one or more cases where the target drug was also prescribed (C1-12 especially i.e. C7L1-30; *The person of ordinary skill in the art at the time the invention was made would have found it obvious for both the "drug" and the "additional drugs" to be prescribed*);

- wherein the one or more prescriptions are configured to result in an adverse drug reaction report (C1-12 especially i.e. “reports of adverse reactions” C6L55-67); and
- wherein the adverse drug reaction is configured so as to be reported in an adverse effects reporting database (C1-12 especially i.e. C5L60-C6L10 or C7L1-55 or C8L14-20 or Figure 4 item 30).

Rationale:

**Szarfman** and **Classen** are from the same field of endeavor, detecting adverse effects of drugs. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of **Szarfman** by comparing the drug to a concomitant drug as taught by **Classen** for the benefit of discovering increased adverse effects of drug combinations (**Classen** C7L1-30).

**Claim 35:**

**Szarfman** teaches:

- wherein the profiler is configured to label each of the one or more drugs as a suspect drug or a non-suspect drug (p1-56 especially i.e. p4 or p51 or p55);
- wherein the profiler is configured to analyze a patient information, the patient information further comprising a plurality of categories for patients whose information is reported in an adverse drug effects reporting database (p1-56 especially i.e. p15-17 or p56);
- wherein the plurality of categories analyzed includes a plurality of age groups, a male gender, a female gender, and a plurality of ages between 16 years old and 75 years old (p1-56 especially i.e. p23 or p27 or p29-30 or p35-37 or p42-43 or p49).

**Classen** teaches:

- wherein the profiler is configured to label each of the one or more drugs as a suspect drug or a non-suspect drug (C1-12 especially i.e. C6L8-C7L30 or C9L10-35);
- wherein the profiler is configured to analyze a patient information, the patient information further comprising a plurality of categories for patients whose information is reported in an adverse drug effects reporting database (C1-12 especially i.e. C3L20-35 or C5L17-35 or C6L35-55 or C7L15-30);
- wherein the plurality of categories analyzed includes a plurality of age groups, a male gender, a female gender, and a plurality of ages between 16 years old and 75 years old (C1-12 especially i.e. C5L17-35 or C6L8-30).

**Claim 38:**

**Szarfman** teaches:

- a pre-filter, wherein the pre-filter is configured in a first state to switch on an indication-related adverse drug reaction (p1-56 especially i.e. p4 or p51 or p55); and
- wherein the pre-filter is configured in a second state to switch off an indication-related adverse drug reaction (p1-56 especially i.e. p4 or p51 or p55).

**Classen** teaches:

- a pre-filter, wherein the pre-filter is configured in a first state to switch on an indication-related adverse drug reaction (C1-12 especially i.e. C6L8-C7L30 or C9L10-35); and
- wherein the pre-filter is configured in a second state to switch off an indication-related adverse drug reaction (C1-12 especially i.e. C6L8-C7L30 or C9L10-35).

**Claim 39:**

**Szarfman** teaches:

- wherein the analysis is **configured** to search for a signal (p1-56 especially p3 or p19 or p25-26 or p32 or p38 or p40 or p50-51 or p56;
- wherein the signal is selected from among the group consisting of an anomaly in a random population reported in an adverse effects reporting database, a change against a known background, or a coherent target in a noise background (p1-56 especially p23 or p32 or p38 or p40); and
- wherein the signal is detected by a proportional analysis engine, a differencing engine, and the correlator (p1-56 especially p23 or p32 or p35 or p42 or p43 or p48 or p49 or p51 or p53).

**Claim 40:**

**Szarfman** teaches:

- wherein the correlator is configured to measure a degree of an association according to a correlation algorithm (p1-56 especially i.e. p23 or p32 or p35 or p42 or p49);

- wherein the correlator is configured to rank a first pair of terms relative to a second pair of terms (p1-56 especially i.e. pp42-44 or p56);
- wherein the correlator is configured to calculate a strength of the association for a known factor and for a rare adverse drug effect (p1-56 especially i.e. p3 or p26 or p32 or p41 or p50); and
- wherein the display presents the results of a correlated search.

**Claim 41:**

**Szarfman** teaches:

- wherein the association is a drug and a reaction **or** a patient age and an outcome (p1-56 especially i.e. pp46-48).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 31 and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Szarfman** ("New Methods for Signal Detection") and **Classen** (USPN 6,219,674) and examiner's **Official Notice**.

**Claim 31:**

**Szarfman** fails to teach:

- a Bayesian filtering, wherein the Bayesian filtering includes providing a statistical cut-off threshold to reduce the effect of the drugs or reactions accounting for less than a certain percentage of cases of adverse drug events.

**Classen** teaches:

- a filtering, wherein the filtering includes providing a statistical cut-off threshold to reduce the effect of the drugs or reactions accounting for less than a certain percentage of cases of adverse drug events (C1-12 especially i.e. C9L10-35).

Rationale:

**Szarfman** and **Classen** are from the same field of endeavor, detecting adverse effects of drugs. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of **Szarfman** by filtering with a threshold as taught by **Classen** for the benefit of establishing acceptable adverse event limits to help determine if the product is commercially viable for a target population (**Classen** C9L10-35).

The combination of **Szarfman** and **Classen** fails to teach:

- the filtering being Bayesian.

The examiner takes **Official Notice** that:

- Bayesian filters were well known to the person of ordinary skill in the art at the time the invention was made and the person of ordinary skill in the art at the time the invention was made would have found it obvious to employ Bayesian filtering for the recited filtering.

**Claim 36:**

**Szarfman** teaches:

- wherein the display is configured to show the one or more drugs labeled as a suspect drug or a non-suspect drug (p1-56 especially i.e. p4 or p51 or p55);
- wherein the display is configured to present a report showing the number of adverse drug effect event reports in each year during a decade (p1-56 especially i.e. p40 or p43 or p48; *The person of ordinary skill in the art at the time the invention was made would have logically understood that the figure on page 48 extends back to 1968 given the figure on page 43*);
- wherein the report is configured to show a plurality of serious outcomes (p1-56 especially i.e. p46-48);
- wherein the report is configured to show serious outcomes in the report in a plurality of colors (p1-56 especially i.e. p46-48);
- wherein the report is configured to provide a table of outcomes and a count of the outcomes in each category (p1-56 especially i.e. pp36-37 or p40 or p43 or 46-48);
- wherein the report is configured to present a total number of serious outcomes and a total number of non-serious outcomes (p1-56 especially i.e. p46-48).

The combination of **Szarfman** and **Classen** fails to explicitly teach:

- wherein a drug detail section of the report involves paging and sorting;
- wherein the report is configured to be broken down into individual years of birth of a patient who experienced an adverse drug effect reported in an adverse drug effects reporting database;
- wherein the report is configured to provide a table of outcomes, a count, and percentages.

The examiner takes **Official Notice** that:

- The person of ordinary skill in the art at the time the invention was made would have found it obvious to involve paging and sorting in the report (such as paging left and right in the figure on page 48 to scroll through all years of data);
- The person of ordinary skill in the art at the time the invention was made would have found it obvious to break the report down into various increments and ranges based on any of the data ranges available in the adverse drug effects reporting database, such as into individual years of birth of a patient who experienced an adverse drug effect reported; and
- The person of ordinary skill in the art at the time the invention was made would have found it obvious for the report to provide percentages of the outcomes in each category.

**Claim 37:**

**Szarfman** teaches:

- wherein the filtering is configured to be applied individually, as a group, and globally (p1-56 especially i.e. p15-17 or p21or p56).

**Classen** teaches:

- wherein the filtering is configured to be applied individually, as a group, and globally (C1-12 especially i.e. C3L20-35 or C5L17-35 or C6L8-30 or C6L35-55 or C7L15-30).

The combination of **Szarfman** and **Classen** fails to explicitly teach:

- wherein the filtering is configured to be retained for later use; wherein the filtering is configured to be applied repeatedly; wherein two or more filters are configured to be merged; wherein the filter is configured to be overwritten; and wherein the filter is configured to be saved as an incremental filter.

The examiner takes **Official Notice** that:

- The claimed aspects of filtering were well known to the person of ordinary skill in the art at the time the invention was made and the person of ordinary skill in the art at the time the invention was made would have found it obvious to employ such filtering techniques in the prior art.

## ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- **Friedman** ("The Safety of Newly Approved Medicines: Do Recent Market Removals Mean There Is a Problem?")
- **Omoigui** ("Observational versus Randomized Medical Device Testing Before and After Market Approval – The Atherectomy-versus-angioplasty Controversy")

Claims 1-5, 7-12, 14-16, and 28-41 are rejected.

## ***Correspondence Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN BUSS whose telephone number is (571)272-5831. The examiner can normally be reached on M-F 9AM-5PM.

As detailed in MPEP 502.03, communications via Internet e-mail are at the discretion of the applicant. Without a written authorization by applicant in place, the USPTO will not respond via Internet e-mail to any Internet correspondence which contains information subject to the confidentiality requirement as set forth in 35 U.S.C. 122. A paper copy of such correspondence will be placed in the appropriate patent application. The following is a sample authorization form which may be used by applicant:

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Vincent can be reached on 571-272-3080. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Benjamin Buss
Examiner
Art Unit 2129

/B. B./
Examiner, Art Unit 2129

/David R Vincent/

Supervisory Patent Examiner, Art Unit 2129